

All you always wanted to  
know about  
**Assurances**

**Office of Research Protections (ORP)**  
**U.S. Army Medical Research and Materiel**  
**Command (USAMRMC)**  
**Fort Detrick, Maryland**  
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# What is an Assurance of Compliance?

It is an official legal written commitment by an institution (private or public entity) made to the Federal Government to comply with the Federal regulations while engaging in research with human participants.

# What is a DoD Assurance of Compliance?

It is an official legal written commitment by an institution (private or public entity) made to DoD to comply with the DoD and HHS regulations while engaging in research with human participants.

Who is required to have  
an approved Assurance of  
Compliance?

Each institution proposing to engage  
in research covered by the Federal Policy  
shall provide written assurance ...  
satisfactory to the...agency head...that it  
will comply with the requirements...in  
this policy.

[see 32 CFR 219.103(a)  
in “the Federal Policy” or the “Common Rule”]

# Who must have a DoD Assurance of Compliance?

DoD requires that -

- all DoD institutions proposing to engage in DoD supported human subject research must have a DoD Assurance, prior to accrual of human subjects.
- a **non**-DoD institution that proposes to engage in DoD-supported human subject research, and does **not** have an FWA, must have a DoD Assurance, prior to accrual of human subjects.

# Who Approves a DoD Assurance?

The Office of the Surgeon General (OTSG) of the Army

32 CFR 219.103(e) - On the basis of its evaluation, OTSG (DoD's designated office) may approve or disapprove the assurance...

# What must be included in an Assurance of Compliance document?

32 CFR 219.103 (b) states that...**Assurances** applicable to federally supported or conducted research **shall at a minimum include**:

- (1) A statement of principles governing the institution...
- (2) Designation of one or more IRBs in accordance with the requirements...
- (3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience. and any relationship with the institution...
- (4) Written procedures which the IRB will follow. . . .
- (5) Written procedures for ensuring prompt reporting to IRB, institutional officials, and the Agency head of (i) any unanticipated problems involving risks to subjects...or any serious or continuing noncompliance with this policy; and (ii) any suspension or termination of IRB approval.

# What are two most “audit-prone” critical features of an Assurance?

- that the institution providing Assurance **has established** written procedures which the IRB will follow...
- that the institution providing Assurance **has established** written procedures to ensure prompt reporting to IRB, DoD officials and other federal agencies of –
  - (i)...unanticipated problems involving risks to subjects...  
...or serious noncompliance with the Federal Policy; and
  - (ii)...termination of IRB approval.

[see 32 CFR 219.103(b)(4) and (5)]



# How is an Assurance connected to an IRB?

An IRB and its membership roster are  
**an integral part**  
of an Assurance.

An Assurance is not complete,  
and may not be approved,  
without including an appropriate IRB as a part of  
it.

# What are the different types of Assurances?

## DOD's Assurances

- Multiple Project Assurance (MPA)
- Single Project Assurance (SPA)  
(domestic; international)

## HHS's Institution based Assurance

- Federal Wide Assurance (FWA)

# Assurance **Renewal** Requirements

To keep an existing Assurance active or current, a renewal must be approved by OTSG:

- before the date of expiration, to remain compliant with the Common Rule for conducting research involving human subjects
- when there is a change in the signatory official.

# Does DoD accept Assurances approved by other Federal Agencies?

Yes.

For non-DoD sites, DoD accepts OHRP-approved

Federal Wide Assurances (FWAs) in lieu of  
DoD Assurances

&

The U.S. Army pursues compliance with DoD specific review requirements through the PI(!)

# Compliance by FWA carrying Institutions with DoD's specific requirements

(!) Food for thought –

- Awards are made to institutions, not to investigators.
- Funding agency needs to ensure that an awardee institution complies with DoD-specific requirements in return for its use of FWA as a substitute for DoD Assurance.
- This will take some burden off the investigator, and put it where accountability legally resides.

# Delegating Review Responsibility to IRB of another DoD Component

In DoDD 3216.2, paragraph 5.3.3 states, "... A DoD component may delegate head-quarters-level research review responsibility to another DoD component for purposes of efficiency and consolidation of functional offices".

This directive permits a DoD institution with an active DoD Assurance to defer IRB review and approval of a protocol to the IRB approval from another DoD Component, such as the Navy or the Air Force.

# What is an IRB Certification?

- It is a written statement, signed by the IRB Chair or designee, that the IRB has reviewed and approved a given study on a given date.
- An investigator may not proceed with human subject accrual in a study prior to receiving this certification from the IRB.

# What must IRB Certification look like?

- It should include information required on OMB Form 0990-0263 [can be found at the website of the Office for Human Research Protections (OHRP)].
- It may be written on the OMB Form, IRB's letter-head stationary or even a plain paper.
- It needs to include complete reference to the reviewed award, e.g., award number; study title; PI's name; institution's name and address; etc.
- It may include the date prior to which the next IRB review and approval are required to occur.



# What Commanders signing & submitting Assurances to DoD must know?

A Commander, who is the signatory on an Assurance from a DoD Research Site, is

accountable for full implementation of and compliance with the Federal Policy and all applicable DoD and Army regulations

as detailed in the Command's DoD Assurance of Compliance document.

# Please note!

Requirement to have an approved and active Assurance of Compliance before engaging in human subjects research is the primary tool

the Federal Government has to enforce compliance with the requirements of the Federal Policy or the Common rule.

What happens if  
a DoD Assurance expires  
without renewal?

The institution is  
no longer authorized to continue  
any DoD supported human subjects  
research.

**What must an institution do**  
if its Assurance expires without  
renewal?

It must suspend all human subject research until the Assurance is renewed, and all protocols are re-reviewed, except when necessary to eliminate apparent immediate hazards to the subjects.

# Why an institution must maintain its Assurance current and itself in compliance?

- Because an Assurance of Compliance is the primary regulatory instrument that the DoD has at its disposal to effect **compliance with the Common Rule** by an institution (public or private).
- Institutional compliance may be forced by actions such as Restriction or Suspension of an Assurance.

# What happens if a DoD Research Site is Audited by the OTSG?

If a DoD's Research Site is audited, and is found -

- not to have an approved and active Assurance; or
- the Research Site is out of compliance with the requirements of the existing Assurance

Then the OTSG may suspend ongoing research and also restrict or suspend an existing active Assurance!

# What happens if a DoD Research Site is Audited by a non-DoD Federal Agency?

If a DoD's Research Site is audited, and is found -

- not to have an approved and active Assurance; or
- the Research Site is out of compliance with the requirements of the existing active Assurance

Then the non-DoD Agency may -

- suspend support of research in question; and
- may report these violations to OTSG of the Army for further action against the Research Site

# **U.S. Army Human Research Protections Office**

*For additional information on how to obtain a DoD Assurance of Compliance please contact:*

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